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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,707	01/28/2004	Jared Floyd	65744/P016US/10316060	3818
29053 7590 07/18/2007 FULBRIGHT & JAWORSKI L.L.P. 2200 ROSS AVENUE SUITE 2800 DALLAS, TX 75201-2784			EXAMINER JAWORSKI, FRANCIS J	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 07/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,707

Applicant(s)

FLOYD ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-13-05 IDS.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6-13-05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1 it is unclear whether the support is being claimed since under one interpretation only an attachment means and a releasable holding device are being claimed. Additionally, it is unclear whether 'a medical device' or 'said needle' (antecedence lacking) govern the scope of the instrument being used therewith. Additionally whereas the preamble pertains to use for activity inside the body the body of the claim pertains to position/alignment prior to actual insertion. That is, the preamble pertains to the in-body positioning whereas the end-claim portion pertains to aiming prior to such positioning. Additionally a 'probe' can be assumed to have a three-dimensional volume such that it is insufficient to define a 'predetermined angle' with respect to a probe in 'toto.

With respect to claim 2 "proximal " is vague, see cl. 24 discussion below.

With respect to claims 6 and 7, the terminology 'over' is vague insofar as no geometric reference is provided (in the sense that pulling a blanket over oneself presupposes reclining.) and it is therefore only inferential for that this pertains to an

outlying radial overlay about the needle, since certain biopsies for example are practiced horizontally(e.g. prostate) and some vertically(e.g. liver).

With respect to claim 9 there is lack of antecedence for 'said probes' (plural). Additionally it is unclear what 'longitudinal' means absent the recitation of a geometric point of reference.

With respect to claim 16, "said medical devices" (plural) lacks antecedence. Additionally "the longitudinal axis" lacks antecedence in terms of a geometric reference: endocavitary probes are elongated in a gun barrel shape; surface probes also have a longitudinal axis to the emission array face (azimuthal direction) which may approach the length of the probe assembly which is orthogonal to the array emission face. [Additionally note that a biopsy needle when within its guide may form an in-plane angle with the long axis (emission face) of the array along the azimuth as per Park et al/Arenson (the latter of record) as well as with the general axis, probe-transducer-tip-to-cable of the probe.]

With respect to claim 24, 28, 35, "the proximal/proximate end" (of the probe) lacks antecedent definition. For example the cable end of a sonic probe may be argued to be proximal/proximate to its image processing system whereas the worksite (e.g. biopsy port) end may be argued to be proximate/proximal to the diagnosis or treatment location.

Dependent claims variously inherit the defects.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 – 5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoi (US4763662) which presents the combination of a pivot attachment means 34, 36 of Figs. 2 – 7 having a proximal and distal pivot 36b,a for attaching a medical device support 32 (or 50) the support in either case having a means such as a channel 46 for holding needle 52 at a predetermined angle with respect to the main ultrasound probe and endoscope, and means 26 for controlling the further egress release of the needle after positioning at a biopsy site within the body.

[Alternately stated, the examiner is applying Yokoi predatory upon the '112 2d issues supra: vagaries regarding angle and whether recited structure acts within or outside the body or both.]

Claims 1 – 10, 24 - 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al (US5924992) insofar as the latter teaches a biopsy needle device support including a support band 3, 'fixed angle' attachment means in the form of slots/tabs 4, 5 which maintain the support band such that the guide portion has fixed angulation, the former (4) of which has a rounded shape so as to serve as a pivot point for snap-fitting the band over the probe, and a finger latch for rotatably sliding around the medical device per movement 7 as shown. The guide portion latches the needle along a longitudinal extent defined in relation to the needle axis with the latch acting

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perpendicular thereto and temporarily holds the needle in a fixed position until release 8 is pressed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 10, 24 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al as argued against claim 1 supra, further in view of Pruter US7087024. In the event that the latch mechanism movement shown as 7 in Park et al be considered to be rotational but not 'sliding' in the sense of this term implying a non-rotational translation type of displacement, then it would have been nonetheless

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obvious in view of Pruter Fig. 2 and col. 3 lines 29 – 45 to utilize a slide 102 for the needle confinement purpose.

Claims 11-12, 27 – 28, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al as applied to claim 9 above, alone (or in the case of claims 24 – 26, further in view of Pruter in an alternative, see above) and further in view of Arenson et al (US5076279, of record). It would have been obvious in view of the latter to use a bracket and pivot point 40 – 43 to mate or separate a guide and probe since this was known to provide reliable fixed angulation to the device. Figs. 9 and 10 show how the slide mechanism as used in Park et al would have an overhang as 21 in order to confine the rod of the needle.

Claims 16 – 21, 23 and 29 - 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Arenson et al and Haerten US4346717 insofar as the latter evidences that early on in the ultrasound guided biopsy instrumentation art once the biopsy guide was fixed in orientation and the needle clampable a trajectory could be plotted such that images of substructures observed while the needle approached them, the later-improved clamping method of Arenson et al allowing greater ease of removal than the initial Haerten clamping and removal approach of col. 4 top.

Claims 35 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arenson et al as applied to claims above regarding clamping and latching, and further in view of Miller et al US5758650 insofar as the latter evidences that it would have been obvious to practice use of a bracket type needle guide as in the former using either

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different angle of attack or a different gauge needle for positioning of the needle under the skin and then removal of the guide. With respect to claim 38 it would have been inherently obvious to package such a set of components together such that they are organized and co-locatable, the packaging providing such a common bond for the grouping.

Allowable Subject Matter

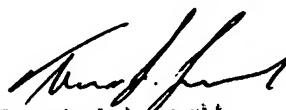
Claims 13 – 15, 22, 33 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Bates et al (US6361499) is cited for its bracket and angle adjustment features.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

071007


Francis J. Jaworski
Primary Examiner